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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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ENFORCEMENT COMMITTEE MEETING

December 10, 2003
9:30 a.m. – 12:30 p.m.
Department of Consumer Affairs
Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Members of the board who are not on the committee may attend and comment during the meeting.

AGENDA

CALL TO ORDER **9:30 a.m.**

A. Discussion Regarding the Reimportation of Prescription Drugs from Canada
Review of Federal Court Decision on Rx Depot – Summit Proposal

B. Discussion Regarding Proposed Citation and Fine Statute for Wholesale Violations and Proposals Regarding Wholesale Drug Transactions

C. Discussion Regarding Recommendation from the MBC/Board of Pharmacy Joint Task Force on Prescriber Dispensing - Proposed Statutory Language to Authorize Dispensing by Medical Groups

D. Discussion Regarding the Implementation of the Enforcement Provisions from SB 361(Chapter 539, Statutes of 2003)

E. Discussion Regarding the Implementation of SB 151 (Chapter 406, Statutes of 2003) – New Prescription Requirements for Controlled Substances and the Elimination of the Triplicate

F. Review of the Quality Assurance Program

G. Overview of the Pharmacists Recovery Program and Probation Monitoring Program - Guidelines for Petitions for Reinstatement, Early Termination of Probation and Reduction of Penalties

H. Meeting Dates for 2004

I. Adjournment **12:30 p.m.**

Committee materials will be available on the board's website by December 3, 2003.

Agenda Item A

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: November 26, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Importation of Prescription Drugs from Canada – Rx Depot Decision - Summit Proposal**

Over the last year, the board has discussed the issue of prescription drug importation from outside of the United States. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings.

During its October meeting, the board decided to hold a summit on prescription drug importation. This summit will be held on April 20th in Sacramento, the day before the April board meeting. The board plans to invite leaders representing all sides of the issue in an effort to fully discuss the health care policy concerns inherent with this topic. This will give board members the broad range of knowledge necessary to plan a course of action to address importation. The board intends to invite the Commissioner of the Food and Drug Administration, the California Attorney General, the president of the Medical Board of California, a nationally recognized pharmacoeconomist who has studied prescription importation, a senior advocacy group representative, and the Rand Corporation.

The goal of the summit is to clarify the issues so that board members have a better understanding of their responsibility in resolving the challenges that have arisen with drug importation.

Meanwhile, on November 6th, the United States District Court for the Northern District of Oklahoma ruled that Rx Depot/Rx Canada violated federal law by causing the importation of prescriptions drugs from Canadian pharmacies. Rx Depot/Rx Canada assists individuals in procuring prescription medications from pharmacies in Canada. Each location has one or two employees who accept prescriptions from U.S. customers. Customers are asked to fill out a medical history form and other forms provided by Rx Depot/Rx Canada. Customers can deliver these documents to Rx Depot/Rx Canada's stores in person, or can mail or fax them to the nearest Rx Depot/Rx Canada store.

Once a Rx Depot/Rx Canada customer has submitted the required forms and prescriptions, the papers and the customer's credit card information or a certified check are transmitted to an operating pharmacy in Canada. A Canadian doctor rewrites the prescription, and the Canadian pharmacy fills the prescription, ships the prescription drugs directly to the U.S. customer, and bills the U.S customer's credit card. Rx Depot/Rx Canada receives a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. They also receive commissions for refill orders, which generally are arranged directly between customers and the Canadian pharmacies. It was noted that Rx Depot/Rx Canada stores are essentially commissioned sales agents for Canadian pharmacies.

The decision called for immediate closing of the 88 nationwide Rx Depot/Rx Canada affiliates, including 17 California locations. Rx Depot/Rx Canada appealed the decision. On November 21st, the 10th Circuit Court of Appeals decision denied the motion from Rx Depot to stay the District Courts ruling.

STATEMENT
November 24, 2003

MEDIA INQUIRIES: 301-827-6242
CONSUMER INQUIRIES: 888-INFO-FDA

STATEMENT ON U.S. COURT OF APPEALS DECISION
DENYING A STAY ON RxDEPOT DECISION

On Friday, November 21, 2003, the 10th Circuit Court of Appeals decision, which denied a motion from RxDepot to stay the District Courts ruling, pending appeal, sent yet another clear signal that those persons, whether public or private, who would put profit before safety will not be allowed to threaten the public health.

Importation of illegal medicines is risky business. Americans should not have to choose between safe products and products that are affordable.

Congress is poised to provide access to safe and affordable drugs for all Americans through actions like a Medicare prescription drug benefit and new laws to improve access to inexpensive generic drugs. Such legislation would help millions of Americans obtain medicines that are both safe and affordable.

FDA is continuing to uphold its longstanding obligation under the law that Congress has given us to protect Americans from illegal drugs that may be unsafe, ineffective, poorly made, substandard or counterfeit.

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Only the Westlaw citation is currently available.

United States District Court,
N.D. Oklahoma.

UNITED STATES of America, Plaintiff,
v.
RX DEPOT, INC. and Rx of Canada, LLC, corporations, and Carl Moore and David Peoples, individuals, Defendants.

No. 03-CV-0616-EA.

Nov. 6, 2003.

Cathryn Dawn McClanahan, United States Attorney, Tulsa, Alan Phelps, U S Dept of Justice, Washington, DC, for United States of America, plaintiff.

Gary L Richardson, Fred Everett Stoops, Sr, Keith Allen Ward, Nancy C Curtis, Richardson Stoops Richardson & Ward, Tulsa, for Rx Depot, Inc., corporation, Rx of Canada, LLC, corporation, Carl Moore, individual, David Peoples, individual, defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

EAGAN, District J.

*1 This matter came on for hearing on October 8-9, 2003, on motion of plaintiff, United States of America, for preliminary injunction against defendants, Rx Depot, Inc., Rx of Canada, LLC, Carl Moore and David Peoples (Dkt.# 2); and motion by defendants for preliminary injunction (Dkt.# 10). Upon consideration of the pleadings and the evidence, the Court finds and concludes as follows:

I. FINDINGS OF FACT

A. *Procedural History*

1. The plaintiff instituted this suit on September 11, 2003, by filing a complaint for injunction (Dkt.# 1) and a motion for a preliminary injunction (Dkt.# 2). Plaintiff's complaint alleged violations by defendants of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § § 331(d) and (t).

2. Defendants filed a response on October 6, 2003 (Dkt.# 10), wherein they moved for their own preliminary injunction against the plaintiff's attempt to enforce the FDCA. Defendants filed an answer and counterclaim on October 8, 2003 (Dkt.# 14).

3. On October 8-9, 2003, the Court heard and received evidence relating to both preliminary injunction motions. Plaintiff and the defendants presented witnesses and exhibits, and thereafter filed proposed findings of fact and conclusions of law.

B. *The Plaintiff*

4. Plaintiff brings this action in its own name pursuant to 21 U.S.C. § 337(a) to preliminarily and permanently enjoin alleged violations of the FDCA by defendants.

C. *The Defendants*

5. Defendant Rx Depot, Inc. ("Rx Depot"), was incorporated under the laws of the State of Nevada on December 2, 2002, and does business at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court. Appendix to Pl. Memorandum in Support of Plaintiff's Motion for Preliminary Injunction ("App.") Ex. A, Tab 1. Rx Depot does business throughout the United States.

6. Defendant Rx of Canada, LLC ("Rx Canada"), is a Nevada limited liability company. Rx Canada is owned by defendant Carl Moore's son, Joe-Max Moore. App. Ex. A, Tab 3.

7. Rx Canada's website, www.rxofcanada.net, is substantially similar to Rx Depot's website, www.rxdepot.com. On the Rx Canada website, links to many purported Rx Canada store locations are actually links to Rx Depot stores, including some stores located in the Northern District of Oklahoma. Similarly, links to some purported Rx Depot locations on the Rx Depot website actually lead to contact information for Rx Canada stores. Transcript of Proceedings, October 8-9, 2003 ("Trans.") at 66-69; Plaintiff's Preliminary Injunction Hearing Ex. ("Pl.Ex.") 11-12.

8. Defendant Carl Moore, an individual, is the President of Rx Depot and a member of its Board of Directors. He has overall responsibility for, and authority over, all operations of the corporation, including the sales arrangements involving ordering, purchasing, and shipment of prescription drugs from Canada. He performs these activities at 4908 South Memorial Drive, Tulsa, Oklahoma, within the

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jurisdiction of this Court. App. Ex. A, Tab 1; Pl.Ex. 6; Trans. at 50, 178.

*2 9. Defendant David Peoples, an individual, is the Secretary of Rx Depot. He is responsible for receiving and processing orders for Rx Depot. He performs these activities at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court. App. Ex. A Tab 1; Pl.Ex. 6.

10. Defendants Carl Moore, David Peoples, Rx Depot, and Rx Canada (collectively, "defendants" or "Rx Depot") operate approximately 85 Rx Depot/Rx Canada stores located throughout the United States, which serve about 800 customers each day. Trans. at 188-89.

D. *Operation of Rx Depot/Rx Canada*

11. Rx Depot assists individuals in procuring prescription medications from pharmacies in Canada. Trans. at 178-79. Each Rx Depot/Rx Canada location has one or two employees who accept prescriptions from U.S. customers. Customers also are asked to fill out a medical history form and other forms provided by Rx Depot. Customers can deliver these documents to defendants' stores in person, or can mail or fax to the nearest Rx Depot/Rx Canada store. Trans. at 20-24, 44-46, 48, 51-52; Pl.Ex. 2, 6, 11-12.

12. Once an Rx Depot/Rx Canada customer has submitted the required forms and prescription to defendants, the papers and the customer's credit card information or a certified check are transmitted to a cooperating pharmacy in Canada. Trans. at 46, 184, 195. A Canadian doctor rewrites the prescription, [FN1] and the Canadian pharmacy fills the prescription, ships the prescription drugs directly to the U.S. customer, and bills the U.S. customer's credit card. Trans. at 22, 45-46, 48, 51-52; Pl.Ex. 6.

> FN1. Based on evidence adduced at the preliminary injunction hearing, such prescriptions may violate Canadian law because the Canadian doctor has no physician-patient relationship with Rx Depot customers. Trans. at 72-73.

13. Defendants receive a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. The defendants also receive commissions for refill orders, which generally are arranged directly between customers and the Canadian pharmacies. Trans. at 189-90; Pl.Ex. 6.

14. Defendants are essentially commissioned sales agents for Canadian pharmacies. Trans. at 191.

15. An Oklahoma state court recently ordered the defendants' stores in Oklahoma to close after finding that the defendants acted as storefronts for Canadian pharmacies and, as such, were operating as unlicensed pharmacies. Trans. at 190-91; Pl.Ex. 25.

16. Defendants admit in their answer to the plaintiff's complaint that they are engaged in the business of causing the shipment of U.S .-manufactured and unapproved, foreign-manufactured prescription drugs from Canadian pharmacies to U.S. citizens. *See* Defendants' Answer and Counterclaims, Dkt. # 14, ¶ 6.

17. The defendants actively solicit other individuals to open "affiliate" Rx Depot/Rx Canada stores by distributing promotional materials that describe their business practices and the potential profits to be made from opening a franchise. Defendants estimate that an affiliate would receive an average 9% commission on each sale of Canadian prescription drugs, about $24.75. The net commissions for an affiliate in the first year would be an estimated $141,570, according to the defendants. Pl.Ex. 1. The defendants' affiliate "Agreement" also states, however, that the service "may at some date be determined to be unlawful or otherwise prohibited." *Id.* at 29.

E. *Prescription Drugs from Foreign Countries*

*3 18. Although defendants presented evidence that the amount of prescription drugs shipped from Canadian pharmacies never exceeds a ninety-day supply, Trans. at 184; Pl.Ex. 24, that defendants do not allow Canadian pharmacies to ship temperature-sensitive drugs, Trans. at 193, and that defendants do not deal with any third parties, Trans. at 194, unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration ("FDA"). Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States. For instance, the drugs may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs

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may have been held under uncertain storage conditions, and therefore be outdated or subpotent. Trans. at 127-28, 141-42, 144; App. Ex. B (McGinnis Decl.) at ¶ ¶ 11, 14.

19. Prescription drugs obtained through Rx Depot frequently are dispensed in greater quantities than are requested by the prescribing physician. Although defendants presented evidence that the amount of prescription drugs shipped from Canadian pharmacies never exceeds a ninety-day supply, Trans. at 184; Govt's Ex. 24, Rx Depot advertises the availability of, and causes the importation of, preset quantities of drugs and dispenses these preset quantities regardless of the quantity of the drug the patient's U.S. physician prescribed and without directions to take the drug for only the number of days prescribed by the U.S. physician. Trans. at 46-47, 62-63, 97-98; Pl.Ex. 10, 11- 12. American patients could, therefore, take a drug for many days more than their physicians intend without supervision. This practice can be dangerous in instances where drugs have potentially life-threatening side effects with continued use. Trans. at 98; App. Ex. C (Katz Decl.) at ¶ 14.

20. Prescription drugs obtained through Rx Depot also do not contain the FDA- approved patient package inserts included with certain prescription drugs in the United States. Nor are prescription drugs obtained through Rx Depot shipped in FDA-approved unit-of-use packaging. This type of packaging is used in the United States to help ensure that certain drugs received by customers arrive in designated dosages with the approved patient package insert. Trans. at 98-104; Pl.Ex. 10, p. 16-17, Ex. 18.

21. The fact that there are currently no known cases of someone being harmed by a drug received as a result of using Rx Depot, Trans. at 137-38, or that plaintiff is currently unaware of anyone being harmed by prescription medications ordered through Rx Depot and imported from Canada, Trans. at 85, does not diminish the legitimate safety concerns of the FDA with unregulated commercial reimportation of U.S.-manufactured drugs by someone other than the manufacturer and importation of foreign-manufactured drugs not approved by the FDA.

F. *Undercover Purchases by FDA*

*4 22. In May 2003, FDA made an undercover purchase through Rx Depot. An FDA investigator in Maryland downloaded the necessary Rx Depot order forms and related paperwork from the Rx Depot website and filled them out as though be were a patient. The investigator also prepared a prescription for 60 pills, to be taken twice a day for 30 days, of the FDA-approved prescription drug Serzone, which is used to treat depression. The prescription allowed one refill. On the Rx Depot form, the investigator ordered a 100-pill package offered on the Rx Depot website rather than the 60 pills indicated on the prescription. Trans. at 46-47, 62-63; Pl.Ex. 9.

23. On May 10, 2003, a second FDA investigator in Oklahoma took the order forms and prescription to an Rx Depot store located at 5801 N. May, Suite 101, Oklahoma City, Oklahoma. The investigator provided the order forms and prescription to the store manager. The Rx Depot manager accepted the paperwork and faxed or mailed the information to a Canadian pharmacy. The manager did not indicate that ordering a greater number of pills than what the prescription called for would be a problem. In fact, the manager stated that drugs obtained through Rx Depot usually came in packages of 100 pills. Trans. at 43-48; Pl.Ex. 8-9.

24. In late May 2003, FDA received a package from Pharmacy North, Inc., in Winnipeg, Manitoba, Canada. The package contained 99 pills (and was labeled as containing 100) of a foreign-manufactured version of Serzone, known as APO- Nefazodone. The labeling provided with the APO-Nefazodone did not direct the patient to take the drug for 30 days or for any other specified period of time. Trans. at 64-65; Pl.Ex. 10.

25. APO-Nefazodone is not generally recognized among qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. Trans. at 93; App. Ex. C (Katz Decl.) at ¶ ¶ 8-11.

26. APO-Nefazodone does not have in effect FDA approval of any new drug or abbreviated new drug applications filed pursuant to 21 U .S.C. § § 355(b) or (j). It does not have in effect a valid exemption from such approval requirements under 21 U.S.C. § 355(i). Trans. at 94; App. Ex. D (Richman Decl.) at ¶ 4.

27. In the United States, Serzone is sold in "unit-of-use packaging" designed to ensure, as much as possible, that the patient receives a designated dose with an FDA-approved patient package insert. The insert includes important information regarding the drug, such as warnings related to potentially serious

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side effects. One potential side effect of Serzone, and generic versions of Serzone such as APO-Nefazodone, involves increased risk of serious liver damage. Trans. at 95, 99, 103; Pl.Ex. 17-18.

28. The labeling provided by the Canadian pharmacy with the APO-Nefazodone included fewer and far less descriptive warnings regarding potential side effects than the FDA-approved patient package insert for Serzone. For example, the Canadian instructions do not specify some of the liver failure symptoms listed on the Serzone insert, do not mention drugs that should be avoided when taking APO-Nefazodone, and do not convey the sense of urgency reflected in the Serzone insert. These substandard instructions could increase the risk of adverse events, including life-threatening liver failure. Trans. at 95, 101-02, 120-21; Pl.Ex. 10, 18.

*5 29. Patient safety also can be compromised when a pharmacy provides more pills than the number prescribed by the doctor. In the case of antidepressants such as Serzone and APO-Nefazodone, potential problems associated with taking a longer-than-prescribed course of medication include increased risk for serious liver problems. Pharmacies in the United States typically do not supply patients with refills until their previous prescriptions are nearly completed. Trans. at 97-98, 106.

30. In late July 2003, an FDA investigator made a second undercover purchase by faxing an order for Sporanox to Rx Depot's Tulsa, Oklahoma, location. Trans. at 20-21; Pl.Ex. 2-3.

31. Sporanox is an FDA-approved prescription drug manufactured in Puerto Rico by Janssen Pharmaceutica, Inc., that is used to treat nail fungal infections. Trans. at 20, 24, 38; Pl.Ex. 5.

32. In early August 2003, FDA received the Sporanox order from Pharmacy North, Inc., in Winnipeg, Manitoba, Canada. The Sporanox was shipped into the United States by a party other than the manufacturer. Trans. at 22-23; Pl.Ex. 4.

33. The drug products purchased by FDA through undercover buys represent just two of the hundreds of prescription drugs advertised on the defendants' websites. Pl.Ex. 11-12.

34. The fact that the FDA did not test for adulteration the individual tablets of APO-Nefazodone or Sporanox received in the undercover purchases, Trans. at 27-29, 40, 76, or that an American pharmacy would have filled the Sporanox prescription, Trans. at 31, is irrelevant to the safety concerns of the FDA at issue in this case. The safety concerns of the FDA relate to reimportation of U.S.-manufactured drugs by someone other than the manufacturer and importation of foreign-manufactured drugs not approved by the FDA. Complaint, Dkt. # 1, at ¶ ¶ 12, 13. Defendant Moore admitted at the hearing that prescription drugs from Canadian pharmacies are not approved by FDA and that some of them are manufactured in the United States. Trans. at 190. Defendants' websites also state that the advertised drugs are not FDA-approved. Pl.Ex. 11-12.

G. *FDA Warnings to the Defendants*

35. On March 21, 2003, FDA issued a Warning Letter to the Rx Depot store located at 200 S. Bloomington, Ste. El, Lowell, Arkansas; copies of the letter were sent to defendants Moore and Peoples. The letter informed the defendants that FDA believed them to be violating 21 U.S.C. § 381(d)(1), because they caused prescription drugs manufactured in the United States to be reimported by persons other than the manufacturer of the drug. Further, the letter stated that the defendants violated 21 U.S.C. § 355 by causing unapproved new drugs to be imported into the United States. Trans. at 69-70, 187-88; Pl.Ex. 13.

36. On May 6, 2003, the defendants responded to FDA's Warning Letter. Defendants stated that all drugs they cause to be obtained from Canadian pharmacies are "manufactured in the United States." Defendants also stated that the drugs advertised on Rx Depot's website and obtained by their customers from Canadian pharmacies " 'are not' FDA approved." Trans. at 70-71; Pl.Ex. 14.

*6 37. In their response to FDA's warnings, defendants did not indicate any intention to halt their illegal practices. By letter dated June 10, 2003, FDA informed the defendants that their response was inadequate. Trans. at 71; Pl.Ex. 14-15.

38. Since receiving the FDA Warning Letter, the defendants have opened approximately 50 additional Rx Depot and Rx Canada stores. Trans. at 190.

39. Defendant Moore testified at the hearing that the defendants would continue their activities unless this Court enjoins them. Trans. at 192.

40. FDA has sent numerous other Warning Letters

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and informational letters to operations similar to Rx Depot and individuals considering engaging in such activities. Pl.Ex. 20. In these letters, some of which pre-date the start of the defendants' business, FDA has consistently stated to interested parties that "a U.S. pharmacy or other business virtually always violates U.S. law by importing or causing the importation of [drugs from Canadian pharmacies]." *Id.* at 8.

H. *Cost of Prescription Drugs*

41. Congress made findings in 2000 regarding the high price of prescription medications in the United States. *See* Medicine Equity and Drug Safety Act of 2000 (the "MEDS Act"), Pub.L. 106-387, § 1(a) [Title VII, § 745(b)], Oct. 28.2000, 114 Stat. 1549, 1549A-35 (codified as amended at 21 U.S.C § § 301, 331, 333, 381, 384 (2000)).

42. The United States ranks significantly higher than other countries, including Canada, in terms of prescription drug costs. Trans. at 8, 132-36, 171, 176, and 213.

43. Because of the high cost of prescription drugs in the United States, some citizens cannot afford their medications at U.S. prices. Defendants presented three highly credible witnesses to testify to this effect at the preliminary injunction hearing. These witnesses use or used Rx Depot to purchase their medications at a significantly lower price. Trans. at 38, 162-66, 171-72, and 199-214. The high cost of prescription drugs in the United States especially impacts those on fixed incomes, such as senior citizens and the disabled. *See id.*

44. American cities and states are either looking at ways to import drugs from Canada, or are already doing so, to alleviate the high cost of prescription drugs on their citizens. Trans. at 130, 161-70, and 173.

45. Congress has found that "efforts to enable such purchases [of prescription drugs at prices comparable to the prices for such medicines in other countries] should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States." MEDS Act, 21 U.S.C.A. § 348, Historical and Statutory Notes, Congressional Finding 5.

46. Not only is Congress the best forum to address the high cost of prescription drugs for U.S. citizens, but also Congress is currently considering legislation which could allow prescription drug importation from Canada.

I. *FDA Personal Use and Enforcement Discretion Policies*

*7 47. The FDA has a personal importation policy which allows entry of foreign drugs by U.S. citizens who bring prescription drugs from foreign countries for personal use. Trans. at 128-29; Pl.Ex. 21; Def. Ex. 1p.

48. The FDA also has an "enforcement discretion policy" whereby the FDA allows small quantities of prescription drugs to be brought into the U.S. by individuals for personal use without recourse. Trans. at 130-31. In this regard, the FDA does not enforce the FDCA against individuals who travel to Canada or use the Internet to purchase prescription drugs from Canada for personal use. Trans. at 35-36, 131, 151, 163, 171, and 175.

49. Any conclusion of law which is more appropriately characterized as a finding of fact is incorporated herein.

II. CONCLUSIONS OF LAW

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. § § 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

2. Venue in this district is proper under 28 U.S.C. § § 1391(b) and (c).

3. The defendants violate 21 U.S.C. § 331 by causing the importation of prescription drugs from Canadian pharmacies.

4. APO-Nefazodone is one of the prescription drugs that the defendants cause to be imported. It is a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and a new drug under 21 U.S.C. § 321(p).

5. Defendants violate 21 U.S.C. § 331(d) each time they cause to be introduced or delivered for introduction into interstate commerce unapproved new drugs in violation of 21 U.S.C. § 355. Specifically, the defendants cause the importation of the unapproved new drugs, such as APO-Nefazodone, listed on their website.

6. Sporanox, another one of the prescription drugs the defendants cause to be imported, is manufactured in Puerto Rico. Pursuant to 21 U.S.C. § 321(a)(1),

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Puerto Rico is a "state" for purposes of 21 U.S.C. § 381(d)(1). Thus, Sporanox is a U.S.-manufactured drug and cannot be imported into the United States by anyone other than the drug's manufacturer.

7. Defendants violate 21 U.S.C. § 331(t) each time they cause the importation of prescription drugs in violation of 21 U.S.C. § 381(d)(1). Specifically, the defendants cause the reimportation of the U.S.-manufactured drugs, such as Sporanox, listed on their website. Reimportation of U.S.- manufactured drugs, even those approved for use in the United States, violates the FDCA, because only the manufacturer of a drug can reimport that drug into the United States. 21 U.S.C. § 381(d)(1).

A. *Preliminary Injunction Standard*

8. Plaintiff seeks a preliminary injunction to stop defendants from further FDCA violations. Generally, an injunction may issue where the movant shows: (1) a substantial likelihood of success on the merits; (2) irreparable injury if the injunction is not granted; (3) that injury outweighs any harm the injunction will cause the opposing party; and (4) the injunction is not adverse to the public interest. *O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 342 F.3d 1170, 1177 (10th Cir.2003); *SCFC ILC, Inc. v.. Visa USA, Inc.*, 936 F.2d 1096, 1098 (10th Cir.1991). Where an injunction would alter the status quo, a heightened standard of scrutiny normally applies. *O Centro Espirita*, 342 F.3d at 1177-78, n. 3.

*8 9. The overriding purpose of the FDCA is to protect the public health. *United States v. An Article of Drug ... Bacto-Unidisk*, 394 U.S. 784, 798 (1969); *United States v. Undetermined Quantities of Bottles ...*, 22 F.3d 235, 238 (10th Cir.1994). It is well settled that where a statute designed to protect the public authorizes injunctive relief, the agency need not prove all of the elements. *See Hecht Co. v. Bowles*, 321 U.S. 321, 331 (1944); *United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 174-75 (9th Cir.1987); *United States v. City of Painesville, Ohio*, 644 F.2d 1186, 1193 (6th Cir.1981); *United States v. Diapulse Corp.*, 457 F.2d 25, 27-28 (2d Cir.1972). Specifically, where an injunction is authorized by statute, as here, the agency to whom the enforcement of the statute has been entrusted is not required to show irreparable harm. *Mical Communications, Inc. v. Sprint Telemedia, Inc.*, 1 F.3d 1031, 1035-36 (10th Cir.1993)(citing *Atchison, Topeka and Santa Fe Railway Co. v. Lennen*, 640 F.2d 255, 259 (10th Cir.1981)); *Odessa Union*, 833 F.2d at 175-76; *Illinois Bell Telephone Co. v. Illinois Commerce Comm'n*, 740 F.2d 566, 571 (7th Cir.1984); *Virgin Islands v. V.I. Paving, Inc.*, 714 F.2d 283, 286 (3rd Cir.1983); *Environmental Defense Fund, Inc. v. Lamphier*, 714 F.2d 331, 338-39 (4th Cir.1983); *Diapulse*, 457 F.2d at 28. Violation of such statutes is presumed to cause public harm; the government need only establish that defendants have violated the statute and there exists "some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *Roe v. Cheyenne Mountain Conference Resort, Inc.*, 124 F.3d 1221, 1230-31 (10th Cir.1997); *Lennen*, 640 F.2d at 260; *Diapulse*, 457 F.2d at 28; *United States v. 22 Rectangular & Cylindrical Finished Devices*, 714 F.Supp. 1159, 1167 (D.Utah 1989)("[h]ere, it is sufficient to warrant an injunction under section 332(a) if it is established that the defendants violated section 331 and that such violations likely will continue").

B. *Status Quo*

10. In *O Centro Espirita*, the Court of Appeals rejected an "absolute" approach to defining the status quo, instead holding that "the definition of 'status quo' for injunction purposes depends very much on the facts of a particular case." *O Centro Espirita*, 342 F.3d at 1178. The status quo need not be the state of affairs immediately preceding litigation. *Id.*

11. Plaintiff contends that, in this case, Congress established the status quo by outlawing the activities in which the defendants now engage. Unlike the facts of *O Centro Espirita* itself, which implicated two seemingly conflicting federal statues, Rx Depot's importation of prescription drugs clearly violates the law. The decision in *SCFC ILC, Inc. v. Visa USA, Inc.*, 936 F.2d 1096 (10th Cir.1991), cited by defendants, is also distinguishable in that it involved a dispute between two private litigants. *Id.* at 1097-98. As set out above, the normal requirements applicable to private litigants do not necessarily apply where, as here, plaintiff seeks to enforce a duly enacted statute designed to protect the public. By definition, such an action can be brought only after the law is broken; where the violation is obvious, preserving the "status quo" as defendants define it would mean protecting illegal activity.

*9 12. Plaintiff has conclusively shown that the relevant statutory provisions explicitly prohibit exactly what the defendants' continue to do. Weighing the particular facts of this case, as required by *O Centro Espirita*, the Court finds that the defendants altered the status quo when they began to build a nationwide business based on violating the

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law.[FN2]

FN2. Contrary to the defendants' assertion, plaintiff did not "admit" that its proposed injunction would alter the status quo; it merely acknowledged the Court's observation that the injunction *might* actually change the status quo. Plaintiff "admitted" that an injunction "would stop the defendants' illegal scheme." Transcript of Proceedings, September 15, 2003, at 9-10. Plaintiff has maintained that an injunction would force the defendants' stores to close, thereby preserving the status quo created by Congress. At the time of the referenced hearing, no legal determination had been made by the Court as to the status quo.

13. Even if plaintiff's motion were construed as an attempt to change the status quo, the relevant preliminary injunction factors as outlined below weigh heavily and compellingly in plaintiff's favor. Applying the heightened standard in this case, therefore, would not change the result. *O Centro Espirita* at 1177-78, n. 3.

C. *Preliminary Injunction Factors*

14. Regarding the first factor, the defendants openly and notoriously violate the law. As previously noted, the defendants admit the relevant facts. Defendants advertise and handle orders for Canadian pharmacies and are remunerated for their efforts. Their actions encouraging and facilitating the illegal importation of drugs amount to a responsible share in the furtherance of these transactions prohibited by the FDCA. Thus, their actions constitute the requisite "causing" under 21 U.S.C. § 331. *See United States v. Dotterweich*, 320 U.S. 277, 284 (1943) (holding liable under FDCA those who have a "responsible share in the furtherance of the transaction which the statute outlaws"); *United States v. Brittain*, 931 F.2d 1413, 1419 (10th Cir.1991) (applying the same rationale to the Clean Water Act). Plaintiff has established more than a substantial likelihood that it will succeed on the merits.

15. The evidence conclusively demonstrates that the defendants' violations will continue absent an injunction by this Court. Defendant Moore admitted that his storefronts would remain open absent a court order. Even aside from this admission, the probability of future violations may be inferred from past unlawful conduct. *Commodity Futures Trading Comm'n v. British American Commodity Options Corp.*, 560 F.2d 135, 142 (2d Cir.1977); *see Odessa Union*, 833 F.2d at 176.

16. As discussed above, weighing the respective harms to the parties is not required here; even were such a test necessary, the defendants would suffer only the "harm" of being ordered to refrain from illegal activity. Despite the defendants' assertions to the contrary, the FDCA is a constitutional exercise of the commerce power. *United States v. Walsh*, 331 U.S. 432, 434 (1947). The defendants have no vested interest in an illegal business activity. *Diapulse*, 457 F.2d at 29 (citations omitted); *see also U.S. v. Articles of Drug*, 825 F.2d 1238, 1248 (8th Cir.1987) (a defendant may not successfully defend against the issuance of an injunction by assertions that the injunction would drive it out of business.).

17. As stated above, plaintiff need only show the defendants' violations of the FDCA in order to prove public harm. "The passage of the statute is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained." *Diapulse*, 457 F.2d at 28 (citing *United States v. City and County of San Francisco*, 310 U.S. 16 (1940)); *see Bioganic Safety Brands, Inc. v. Ament*, 174 F.Supp.2d 1168, 1179 (D.Colo.2001) (holding in a preemption case that fourth factor is satisfied where Congress has determined the public interest). Here, Congress explicitly found that the unrestricted reimportation of U.S.-manufactured drugs created "an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers." PL 100-293, Sec. 2 ("Findings"), April 22, 1988 (available on Westlaw at 102 Stat. 95). Defendants' contention that FDA's enforcement action would not actually protect the public from anything is not supported by the record and, moreover, irrelevant. *See United States v. Undetermined No. of Unlabeled Cases*, 21 F.3d 1026, 1028 (10th Cir.1994) ("The focus of this Court's inquiry is whether the Act empowered the FDA to take the actions it did and not the efficacy of those actions."). Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for the courts to enforce them when asked. *TVA v. Hill*, 437 U.S. 153, 194 (1978).

*10 18. The Court recognizes that individual customers of the defendants believe that they benefit from the low prescription drug prices offered by Rx Depot/Rx Canada. This Court is not unsympathic to

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the predicament faced by individuals who cannot afford their prescription drugs at U.S. prices. However, the defendants are able to offer lower prices only because they facilitate illegal activity determined by Congress to harm the public interest. Congress, not this Court, is the best forum for weighing all of the costs and benefits of the national statutory scheme regulating prescription drug importation. *Cf.* *United States v. 9/1 Kg. Containers, More or Less, of an Article of Drug for Veterinary Use*, 854 F.2d 173, 179 (7th Cir.1988) ("Subjects such as these [FDA approval and certification process] are for Congress and the FDA to consider. Judges' role is to decipher and enforce the existing scheme, whatever they think of its wisdom.").

D. *Selective Enforcement Claim*

19. Defendants' claim of unconstitutionally selective enforcement by FDA is unavailing. FDA's personal importation policy outlines specific circumstances in which the agency generally will decline to prosecute the illegal importation of small quantities of prescription drugs by individuals. By its express terms, this policy of enforcement discretion does not apply to commercial operations such as Rx Depot/Rx Canada. *See* Pl.Ex. 21.

20. Moreover, the Supreme Court has held that "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." *Heckler v. Cheney*, 470 U.S. 821, 831 (1985). To prevail on a claim of selective prosecution, therefore, the defendants must show that others similarly situated have not been subject to enforcement proceedings by the government, and that there was a constitutionally impermissible basis for the decision to institute enforcement action against the defendants such as race, religion, or other arbitrary classification. *United States v. Armstrong*, 517 U.S. 456, 464-65 (1996) (citing *Oyler v. Boles*, 368 U.S. 448, 456 (1962)); *Wayte v. United States*, 470 U.S. 598, 608 (1985). Defendants have made no such showing here. Instead, the defendants point to FDA's failure to prosecute all individuals who cross the Canadian border on their own or use the Internet to buy their prescription drugs. Defendants claim that this fact evidences some vague policy of "geographical" discrimination. It is reasonable, however, for FDA to marshal its limited resources against large-scale, commercial operations such as Rx Depot/Rx Canada rather than small-scale, individual violators.

21. The Congressional intent referred to in Findings of Fact 41 and 45, *supra*, expressly conditioned the implementation of the MEDS Act on a determination by the Secretary of Health and Human Services that the envisioned new system would pose no additional health risks to U.S. consumers, and that it would result in significant cost savings to the American public. 21 U.S.C. § 384(1). The current and previous HHS secretaries have not made such a determination. Pl.Ex. 22; Trans. at 133, 139.

E. *Defendants' Remaining Claims*

*11 22. Defendants' remaining arguments and counterclaims similarly do not justify affirmative relief nor do they override plaintiff's interest in enforcing the law.

23. Defendants argue that plaintiff's enforcement actions violate the Privileges and Immunities Clause, U.S. Const., art. IV, § 2. The Privileges and Immunities Clause does not apply here; the Clause requires a State to accord residents and non-residents equal treatment when regulating the means of livelihood or doing business. In any event, the defendants have not shown that they have a privilege or fundamental right to facilitate illegal prescription drug importation. *See* *Supreme Court of New Hampshire v. Piper*, 470 U.S. 274, 279 (1985).

24. Likewise, the facilitation of such imports, even to the extent it involves "speech," is not protected by the First Amendment. *See* *United States v. Pinelli*, 890 F.2d 1461, 1472 (10th Cir.1989) (illegal conduct not protected simply because it involves speech) (citing *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)); *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 389 (1973) (any First Amendment interest in advertising a commercial transaction is "altogether absent when the commercial activity itself is illegal and the restriction on advertising is incidental to a valid limitation on economic activity.").

25. The North American Free Trade Agreement, as defendants conceded at the hearing, provides no remedy to private citizens. 19 U.S.C. § 3312(c); Trans. at 13.

26. Finally, the Court's equitable powers are not appropriately invoked. It would be an abuse of the Court's equitable power to ignore statutory law, or to declare a statute invalid where there is no constitutional basis for doing so. "A district court cannot ... override Congress' policy choice,

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articulated in a statute, as to what behavior should be prohibited. 'Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is ... for the courts to enforce them when enforcement is sought." ' *United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 497 (2001) (quoting *TVA v. Hill*, 437 U.S. 153, 194 (1978)).

III. CONCLUSION

27. FDA warned the defendants that their violations would subject them to enforcement action. Notwithstanding this warning, the defendants failed to comply with the FDCA; in fact, they expanded their operations. Unless restrained by order of this Court, the defendants will continue to violate 21 U.S.C. § § 331(d) and (t).

28. Plaintiff's motion for a preliminary injunction (Dkt.# 2) is granted.

29. For the same reasons described herein, defendants' motion for a preliminary injunction (Dkt.# 10) is denied.

30. Plaintiff's motion in limine (Dkt.# 11) is granted as to lay testimony regarding safety and effectiveness of particular drugs, and denied as moot as to all other evidence sought to be excluded.

*12 31. Any finding of fact which is more appropriately characterized as a conclusion of law is incorporated herein.

ORDER OF PRELIMINARY INJUNCTION

Plaintiff, United States of America, having filed a complaint for injunction and a motion for preliminary injunction against defendants Rx Depot, Inc. and Rx of Canada, LLC, corporations, and Carl Moore and David Peoples, individuals (collectively "defendants"); and defendants having filed their own motion for preliminary injunction; and the Court having heard the evidence at a hearing on October 8-9, 2003; and the Court having considered the pleadings, the evidence, and arguments of counsel, and having entered its findings of fact and conclusions of law simultaneously herewith; and it appearing that the defendants are violating and, unless restrained by order of this Court, will continue to violate the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § § 331(t) and (d), by importing, or causing importation of, drugs in violation of 21 U.S.C. § 381(d)(1), and by introducing or delivering for introduction, or causing to be introduced or delivered, into interstate commerce unapproved new drugs; and it appearing that, despite repeated warnings that their actions violate the law, the defendants will not stop these illegal practices unless enjoined by the Court; and it appearing that the defendants' practices expose the public health to risk.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter herein and has personal jurisdiction over all parties to this action.

2. The complaint for injunction states a cause of action against the defendants under the Act, 21 U.S.C. § 301 *et seq.*

3. There is a substantial likelihood that plaintiff will succeed on the merits of its claim that the defendants violate 21 U.S.C. § 331(t), by importing, or causing to be imported, into the United States drugs that were manufactured in the United States by persons other than the defendants, in violation of 21 U.S.C. § 381(d)(1).

4. There is a substantial likelihood that plaintiff will succeed on the merits of its claim that the defendants violate 21 U.S.C. § 331(d), by doing or causing the introduction or delivery for introduction into interstate commerce of drugs that are new drugs within the meaning of 21 U.S.C. § 321(p), that have not been approved by the Food and Drug Administration ("FDA"), in violation of 21 U.S.C. § 355(a).

5. The defendants and each and all of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities) who have received actual notice of this Order by personal service or otherwise, are hereby preliminarily restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing, during the pendency of this action, the introduction, or delivery for introduction, into interstate commerce, including, but not limited to, the importation of, any article of drug, and from directly or indirectly receiving any commission associated with the refill of any prescription.

*13 6. Upon the entry of this Order, the persons and entities identified in the preceding paragraph shall cease offering, advertising, or promoting, through

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any media, including, but not limited to, the websites www.rxdepot.com and www.rxofcanada.net, any service that causes or facilitates the importation or assistance in importing articles of drug from any place outside the United States.

7. Within 10 calendar days of entry of this Order, the defendants shall send a letter, which must be approved in advance in writing by FDA, to all of their customers notifying them that the defendants' business violates the law and that the safety, purity, and efficacy of drug products obtained through the defendants cannot be assured.

8. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA investigators shall be permitted access to all equipment, finished and unfinished drugs, and all labeling, including promotional materials and website information; to take photographs and make video recordings; to take samples of the defendants' finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to product formulation, adverse reactions, complaints, the relationship between defendants and their franchisees, affiliates, and "doing business as" entities, the ordering of prescription drugs from Canada and any other countries, and the receipt, processing, labeling, packing, manufacture, and distribution of any product. Such inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to conduct inspections under 21 U.S.C. § 374.

9. The defendants shall provide a copy of this Order, by personal service or registered mail, within 10 calendar days of its entry, to each of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including all franchisees, affiliates, and "doing business as" entities). The defendants shall provide an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the first sentence of this paragraph, and identifying the names and positions of all persons so notified, to FDA within 30 calendar days after the date of entry of this Order. All physical locations and websites shall be identified as such in this written affidavit to FDA.

10. If the defendants or any of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including, but not limited to, franchisees, affiliates, and "doing business as" entities) violate this Order and are found in civil or criminal contempt thereof, the defendants shall, in addition to other remedies, pay attorney fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred by plaintiff in bringing such action.

2003 WL 22519473, 2003 WL 22519473 (N.D.Okla.)

END OF DOCUMENT

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Agenda Item B

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: November 25, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Proposed Citation and Fine Statute for Wholesale Violations and Proposals Regarding Wholesale Transactions**

At the July Enforcement Committee meeting, Supervising Inspector Judi Nurse gave an overview regarding bid contract diversion in California. Pharmacies purchase "bid contract" drugs at special prices and then through a common ownership transfer the drugs to its wholesale facility to be resold to other wholesalers. Often times, there is no record for these drug transactions. The drugs are resold several times through many wholesalers and many states in largely undocumented transactions that are impossible to trace. This "gray market" system has allowed for counterfeiting which is the dilution, mislabeling or adulteration of drugs. The unscrupulous companies can turn one shipment of injectable medications into many by watering down the drugs and reproducing the packaging.

The issue of bid contract diversion and the proliferation of counterfeit drugs have caused the committee to propose regulations to ensure the integrity of California's drug distribution system. The committee began its discussion this issue last year and comments were made that the regulation would impede legitimate business transactions and modifications were suggested. It was also stated that the federal PDMA allows for intra-company sales, which may be contrary to the proposal. While the board had been using Nevada as its model for the regulatory framework, it was suggested that the committee might want to review the Florida legislation. The new Florida law identifies a list of drugs that requires due diligence in authenticating prior transactions on pedigrees.

Chair John Jones requested interested parties to submit proposed language to address the concerns that were discussed; however, none have been provided. Therefore, staff prepared a new regulatory proposal to address wholesale and pharmacy transactions. In addition, a legislative proposal was prepared for citation and fine authority for wholesale violations. It was explained that the legislative proposal was intended to seek monetary sanctions for economic motivations for law violations. While the board can pursue cases administratively for these same violations, usually by the time any formal action is pursued, the wholesaler permit is cancelled and the board has no authority over the non-licensed owners.

There was considerable discussion regarding the burden that the proposed regulations would place on the wholesaler. Currently, drugs are not tracked by lot numbers and it was expressed that it would be unreasonable for the board to limit the sale or transfer of a drug to three times prior to being furnished to the final consumer. It was unclear as to the magnitude of the problem and the committee asked staff to provide documentation at its next meeting in December before making a recommendation to the board. Since the last meeting, there have been numerous articles on this issue of counterfeit drugs and wholesale distributors.

Staff has prepared background material to display the type of cases that it has investigated over the years. Also, we have reworked and expanded some of the legislative proposals.

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: December 2, 2003

From: Paul Riches

Subject: Draft Changes for Wholesalers

The enforcement committee has been engaged in a process of developing rules designed to strengthen the regulation of drug wholesalers for some time. A number of different proposals have been considered by the committee. Based on discussions at prior committee meetings and discussion at the October 2003 board meeting, staff has developed the attached proposal for the committee's consideration. The proposal includes elements that have been considered previously, most notably expanded citation and fine authority for certain violations, and elements drawn from recent legislation passed in Florida. The recent Florida legislation focused on preventing the introduction of counterfeit drugs into the system by implementing stricter licensing requirements for drug wholesalers, increasing the criminal sanctions for counterfeiting prescription drugs, and by requiring pedigrees.

The attached proposal is designed to address challenges in the presented by the existing distribution system for prescription drugs. The proposal also includes changes to wholesale licensing requirements approved by the board at its October 2003 meeting. The principal elements are as follows:

1. Require pedigrees for all drug shipments beginning January 1, 2006.
2. Generally prohibiting the wholesaling of prescription drugs by pharmacies.
3. Require wholesalers to obtain a $100,000 bond to secure payment of administrative fines and penalties.
4. Permit the board to issue fines on a per occurrence basis for specified violations (e.g., sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.)
5. Defines "closed door pharmacy" as one serving skilled nursing and intermediate care facilities and prohibits the owners of a closed door pharmacy from owning a wholesaler.

Board of Pharmacy
Draft Revisions to Wholesaler Statutes

Add Section 4021.5 to the Business and Professions Code, to read:

4021.5. "Closed Door Pharmacy" means a pharmacy that only serves patients in a skilled nursing or intermediate care facility. A closed door pharmacy may not dispense dangerous drugs or dangerous devices to a person not receiving care in either a skilled nursing or intermediate care facility.

Add Section 4034 to the Business and Professions Code, to read:

4034. "Pedigree" means a document containing information that records each distribution of any given dangerous drug or dangerous device, from sale by a manufacturer, through acquisition and sale by any wholesaler, until final sale to a pharmacy or other person administering or dispensing the drug. A pedigree shall include:

(a) quantity
(b) dosage form and strength
(c) lot numbers
(d) the name, address, signature, and California license number of each licensee possessing the dangerous drugs or dangerous devices
(e) shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug or dangerous device,
(f) a certification that the recipient has authenticated the pedigree papers.
(g) the name, address, California license number, and telephone number for each wholesaler involved in the chain of custody for the dangerous drug or dangerous device.

Add Section 4126.5 to the Business and Professions Code, to read:

4126.5. (a) A pharmacy may only furnish dangerous drugs or dangerous devices as follows:

(1) To the wholesaler or manufacturer from whom the dangerous drugs or dangerous devices were acquired.
(2) To a licensed reverse distributor.
(3) To another pharmacy or wholesaler to alleviate temporary shortages that could result in the denial of healthcare.
(4) To a patient or a provider of health care, other than a pharmacy, authorized to purchase dangerous drugs and dangerous devices.

Amend Section 4160 of the Business and Professions Code, to read:

4160. (a) No person shall act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
~~(b) No selling or distribution outlet, located in this state, of any out-of-state manufacturer, that has not obtained a license from the board, that sells or distributes only the dangerous drugs or the dangerous devices of that manufacturer, shall sell or distribute any dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.~~
(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.
(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.
(f) Notwithstanding any other provision of law, the board shall not issue or renew a wholesaler license if the applicant is a person beneficially interested, as defined in Section 4201, in a closed door pharmacy.
(g) An applicant for a wholesaler license or an applicant for the renewal of a wholesaler license must submit a bond of $100,000 payable to the Pharmacy Board Contingent Fund. A separate bond shall be provided for each location. The purpose of the bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3. The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or costs become final.
(h) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships drugs of its own manufacture is exempt from this section.

Repeal Section 4161 of the Business and Professions Code:

~~4161. (a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out-of-state dangerous drug or dangerous device distributor's license.~~
~~(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.~~
~~(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer or wholesaler.~~
~~(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.~~

Add Section 4161 to the Business and Professions Code, to read:

4161. (a) No person shall act as a non-resident wholesaler without possessing a nonresident wholesaler license from the board.
(b) Any person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) An applicant for a nonresident wholesaler license shall disclose to the board the location, names, and titles of:

(1) Its agent for service of process in this state.
(2) Principal corporate officers as specified by the board.
(3) General partners as specified by the board.

(e) A report containing the information required in subdivision (d) shall be made to the board within 30 days of any change of office, corporate officer, or partner.

(f) All nonresident wholesalers shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is located as well as with all requests for information made by the board.

(g) All nonresident wholesalers shall maintain records of dangerous drugs or dangerous devices sold, traded or transferred to persons in this state so that the records are in a readily retrievable form.

(h) The nonresident wholesaler shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the wholesaler in compliance with the laws of the state in which it is a resident. Applications for a nonresident wholesaler license shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board shall not issue or renew a nonresident wholesaler license until an exemptee-in-charge is designated and the board is notified in writing of the identity and license number of that exemptee.

(j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. Each nonresident wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge.

(k) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) An applicant for a nonresident wholesaler license or an applicant for the renewal of a nonresident wholesaler license must submit a bond of $100,000 payable to the Pharmacy Board Contingent Fund. A separate bond shall be provided for each location. The purpose of the bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3. The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or costs become final.

Repeal Section 4162 of the Business and Professions Code:

~~4162. (a) No person acting as principal or agent for any out-of-state manufacturer, wholesaler, or pharmacy who has not obtained a license from the board, and who sells or distributes dangerous drugs or dangerous devices in this state that are not obtained through a wholesaler who has obtained a license, pursuant to this chapter, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler, pursuant to this chapter, shall conduct the business of selling or distributing dangerous drugs or dangerous devices within this state without registering with the board.~~

~~(b) Registration of persons under this section shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose dangerous drugs or dangerous devices he or she is selling or distributing.~~

~~(c) The board may deny, revoke, or suspend the person's registration for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The board may deny, revoke, or suspend the person's registration if the manufacturer, whose dangerous drugs or dangerous devices he or she is selling or distributing,~~

~~violates any provision of this chapter or any provision of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The registration shall be renewed annually.~~

Amend Section 4163 of the Business and Professions Code, to read:

4163. (a) Dangerous drugs or dangerous devices shall only be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.
(b) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.
(c) On and after January 1, 2006, no wholesaler or pharmacy shall sell, trade, or transfer a dangerous drug or dangerous device without providing a pedigree.
(d) On and after January 1, 2006, no wholesaler or pharmacy shall acquire a dangerous drug or dangerous device without receiving a pedigree.

Amend Section 4165 of the Business and Professions Code, to read:

4165. (a) Any manufacturer or wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.
(b) Any manufacturer who fails within a reasonable time, or refuses, to comply with subdivision (a), shall be subject to citation and a fine, an order of abatement, or both, pursuant to Section 125.9 and any regulations adopted by the board, in addition to any other remedy provided by law.

Amend Section 4166 of the Business and Professions Code, to read:

4166. (a) Any wholesaler ~~or other distributor~~ that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

Add section 4168 to the Business and Professions Code, to read:

4168. A county or municipality shall not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.

Add Section 4169 to the Business and Professions Code, to read:

4169. (a) Notwithstanding any other provision of law, a the following violations may subject, in addition to any other remedy provided by law, the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board:

(1) Violation of Section 4126.5.
(2) Violation of Section 4163.
(3) Purchase, trade, sell or transfer drugs or devices that are adulterated as defined in Health and Safety Code Division 104, Part 5, Chapter 6, Article 2.

(4) Purchase, trade, sell or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

Agenda Item C

State of California Department of Consumer Affairs

Memorandum

To: **Enforcement Committee** **Date: November 25, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Medical Board of California (MBC)/Board of Pharmacy Joint Task Force on Prescriber Dispensing**

The Medical Board of California (MBC) and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. Board President John Jones and Stan Goldenberg represented the board. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the record keeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004. Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments. The proposal would require a special clinic licensure for these group practices, which would have a fiscal impact to the board.

At the September Enforcement Committee meeting, the interested parties expressed concern that they had just received the proposed language and did not have sufficient time to review it and provide comment. There was also discussion that consensus was not reached on this issue contrary to the statement made by the task force. The Enforcement Committee agreed to discuss this issue at its December meeting so that the interested parties had sufficient time to review the proposal.

Board of Pharmacy
Prescriber Dispensing Reform
Concept Draft – September 16, 2003

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed, by the prescriber, to the prescriber's own patient. A registered nurse may hand to the patient the dangerous drugs or dangerous devices dispensed by the prescriber. ~~, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.~~

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice. This disclosure shall include information relating to the availability of generic drug alternatives and a statement that the drugs dispensed may be available at lower cost through purchase at a pharmacy.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may ~~hand~~ furnish dangerous drugs or dangerous devices to a patient. ~~of the supervising physician and surgeon a properly labeled prescription drug, prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.~~

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, or a certificate to practice podiatry, and who is duly registered as such by the Medical Board of California, the State Board of Optometry, the Dental Board of California, or the Board of Osteopathic Examiners of this state.

Article 13 – ~~Non-Profit or Free~~ Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a prescriber ~~physician~~, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(G) A group practice.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued ~~to a specific clinic and~~ for a specific location.

(c) For the purposes of this article, "group practice" means more than one prescriber operating a practice providing health care services at a specific location.

(e) Prescribers in a group practice shall maintain the following information for each prescription on file and this information shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing prescriber.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label.

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing prescriber.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(f) This section shall not apply to an individual prescriber practicing at a licensed location who dispenses drugs from the prescriber's personal stock of dangerous drugs and dangerous devices only to the prescriber's patients pursuant to Section 4170.

4181. (a) (1)Prior to the issuance of a clinic license authorized under Section 4180 (a)(1)(A) – (F), the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(2) Prior to the issuance of a clinic license authorized by 4180(a)(1)(G), the group practice shall

comply with all applicable laws and regulations relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist and the professional director of the group practice.
(b) ~~These~~ The policies and procedures required by this section shall include a written description of the method used in developing and approving them and any revision thereof.
(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
(b) The consulting pharmacist shall certify in writing at least twice a year that the clinic is, or is not, operating in compliance with the requirements of this article. The clinic shall maintain these written certifications in the clinic for at least three years. ~~, and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license.~~
(c) For the purposes of this article, "professional director" means a ~~physician~~ prescriber acting in his or her capacity as ~~medical~~ professional director.

4183. No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

4184. ~~No Schedule II controlled substance shall be dispensed by the clinic. This limitation shall not be construed to prohibit a physician dispensing a Schedule II drug to the extent permitted by law.~~ Clinics that dispense Schedule II and Schedule III controlled substances shall report those prescriptions to the CURES program pursuant to Section 11165 of the Health and Safety Code.

4185. The board, and any other authorized officer of the law, shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.

4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug delivery system is ~~being~~ used.
(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for

potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.
(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
(f) The pharmacist operating the automated drug delivery system shall be located in California.
(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.
(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

4187. (a) Notwithstanding any other provision of law, an automated drug delivery system located in a clinic licensed pursuant to Section 4180(a)(1)(G) shall be owned and operated by a licensed pharmacy.
(b) Notwithstanding any other provision of law, a pharmacist may supervise a single pharmacy technician at a remote location where an automated drug delivery system is operated in a clinic licensed pursuant to Section 4180(a)(1)(G), and this pharmacy technician shall not be subject to the ratio established in Section 4115.

Agenda Item D

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: November 26, 2003**

From: **Patty Harris**
Executive Officer
Board of Pharmacy

Subject: **Implementation of Compliance Provisions from SB 361**

SB 361 (Figueroa) was the legislative vehicle for the Board of Pharmacy sunset extension and contained statutory recommendations approved by the Joint Legislative Sunset Review Committee. The following compliance provisions will be added to California Pharmacy Law effective January 1, 2004.

- **Add Section 4083 – Order of Correction**

Will allow an inspector to issue an order of correction to a licensee directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector, or the licensee can contest the order of correction to the executive officer for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. A copy of the order of correction and corrective action plan must be maintained on the license premise for at least three years from the date the order was issued.

- **Add Section 4315 – Letter of Admonishment**

Will authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with pharmacy law and directs the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the licensed premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment will be considered a public record for purposes of disclosure.

- **Add Section 4314 – Issuance of Citations**

Will allow the board to issue an order of abatement that will require a person or entity to whom a citation has been issued to demonstrate how future compliance with the pharmacy law will be accomplished and provides that such demonstration may include, but not be limited to,

submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

These new changes will be incorporated into the board's investigation process as follows:

During a routine inspection or investigation, if it is believed that a violation of pharmacy law took place, the licensee may be advised of the alleged violation by an "Order of Correction," directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector. This process will simply notify the licensee of the violations of law that the inspector believes occurred. This notification may not the board's final or formal determination regarding the matter depending on the seriousness of the alleged violation. It is also neither a citation nor is it a disciplinary action.

At this time, the licensee will be provided the opportunity to provide a written response to the alleged violation. In the written response, the licensee may address the specifics of the violation, as well as provide any mitigatory information that the licensee wishes to have included in any investigation report and/or a corrective action plan.

If the "Order of Correction" is for minor violations, and the inspector is satisfied with the pharmacy's compliance, the "Order of Correction" may be the only action taken. If this is the case and the pharmacy doesn't contest the order, then the licensee must maintain on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date the order was issued.

After the inspection or investigation is completed and there is a determination that the law was violated, the case is referred to a supervising inspector for review. If the supervising inspector determines that there was no violation or that the violation was so minor that the only action to take would be the issuance of the "Order of Correction", then the case may be closed and the matter goes no further.

If, after review by the supervising inspector, it is determined that action may be warranted, the case is referred to the executive officer. The executive officer, with the assistance of the supervising inspector, reviews the matter and determines the appropriate course of action. In making this determination, the following factors may be taken in consideration:

- Gravity of the violation.
- Good or bad faith of the cited person or entity.
- History of previous violations.
- Evidence that the violations were or were not willful.
- Recognition by the licensee of his/her wrongdoing and demonstration of corrective action to prevent recurrence, e.g., new policies and procedures, protocol, hiring of additional staff, etc.
- Extent to which the cited person or entity has cooperated with the Board's investigation and other law enforcement or regulatory agencies.
- Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- If the violation involved multiple licensees, the relative degree of culpability of

each licensee should be considered. In the case where a staff pharmacist may have failed to consult, the pharmacist-in-charge and the pharmacy may also be issued a citation and fine, if warranted by the circumstances.

- Any other relevant matters that may be appropriate to consider.

The type of potential action include:

- **Further Investigation**

The executive officer may decide that there is insufficient evidence to determine if a violation occurred or if any action is warranted. The executive officer may then send the matter back for further investigation.

- **Case Closure – No Further Action**

The executive officer may decide that no action is now warranted. This may occur when the executive officer determines that there was no violation, that the violation was so minor as to not merit an action, or that the mitigating circumstances were such that it would be best not to pursue an action. The matter will then not be taken any further. (The final resolution would be the "Order of Correction".)

- **Letter of Admonishment**

The executive officer may decide to issue a letter of admonishment. This may occur when the executive officer determines that there was a minor violation, or a violation that mitigating circumstances were such that a letter of admonishment was appropriate. The licensee would be directed to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference.

If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the licensed premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment would be considered a public record for purposes of disclosure.

- **Citation and Fine**

The executive officer may issue a citation, with or without a fine. The citation will be issued to the licensee and will include a reference to the statute or regulation violated. It will also include a description of the nature and facts of the violation, as well as a notice to the licensee of the appeal rights. It may or may not include an order of abatement either requesting documentation of the licensee's compliance, or directing the licensee to come into compliance and specifying how that must be done.

- **Disciplinary Action**

The executive officer may determine that the violation is substantial and warrants discipline of the license. The matter is then referred to the Attorney General's Office, where, if appropriate to do so, an accusation is prepared, which identifies the alleged violations of pharmacy law.

Agenda Item E

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: November 25, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Implementation of SB 151**

Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and substantially revises California law regarding the prescribing of controlled substances generally. This memo will outline the changes contained in this legislation. Generally, this bill repeals the triplicate and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions after the phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

EFFECTIVE JANUARY 1, 2005

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions (oral and fax orders for Schedules III-V are still permitted) shall be on the new controlled substance prescription forms.
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2)

IMPLEMENTATION PHASE I
January 1, 2004 – June 30, 2004

- The Board of Pharmacy (board) and the Department of Justice (Department) may approve security printers to produce the new controlled substance prescription forms.

- California mail order pharmacies can apply the prescription requirements of the state in which the patient resides when filling schedule II prescriptions.

- Controlled substance prescriptions (Schedules II-V) are valid for six-months.

- Makes CURES permanent and requires all pharmacies to report Schedule II controlled substance prescriptions to the Department of Justice

- Prescribers only need to sign and date Schedule III-IV controlled substance prescriptions (consistent with current Schedule II prescription requirements)

- New controlled substance prescription forms may be acquired from approved security printers.

- Requires the new controlled substance prescription forms to have the following features:
  (1) Latent "void" protection so that if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
  (2) Watermark with the text "California Security Prescription" printed on the back of the prescription.
  (3) Chemical void protection that prevents alteration by chemical washing.
  (4) Feature printed in thermo-chromic ink (the ink changes color when exposed to heat).
  (5) Feature using micro printing (the text becomes a line if the prescription is copied or scanned).
  (6) Description of the security features included on each prescription form.
  (7) Quantity check off boxes printed on the form in the following quantities: 1-24, 25-49, 50-74, 75-100, 101-150, 151 and over.
  (8) Either of the following statements:
    (a) "Prescription is void if more than one controlled substance prescription is written per blank" or
    (b) Contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
  (9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
  (10) A check box indicating the prescriber's order not to substitute.
  (11) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

IMPLEMENTATION PHASE II
July 1, 2004 – December 31, 2004

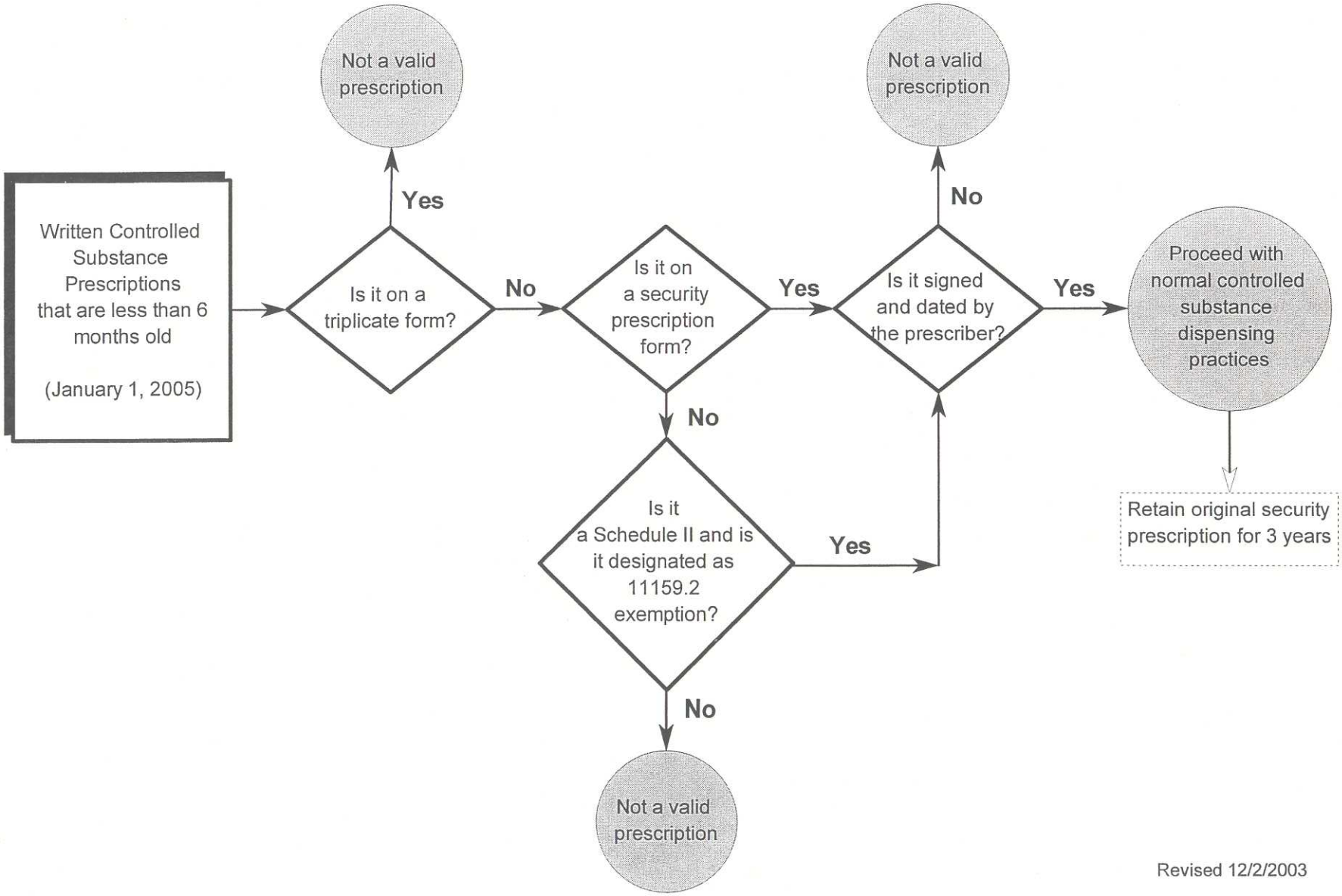
- The Department of Justice no longer will produce or distribute triplicate prescription forms. However, prescribers can continue to use the triplicate prescription forms to prescribe Schedule II controlled substances.

- Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.

- Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted and must be reduced to a hard copy form of the pharmacy's design and signed by the pharmacist.

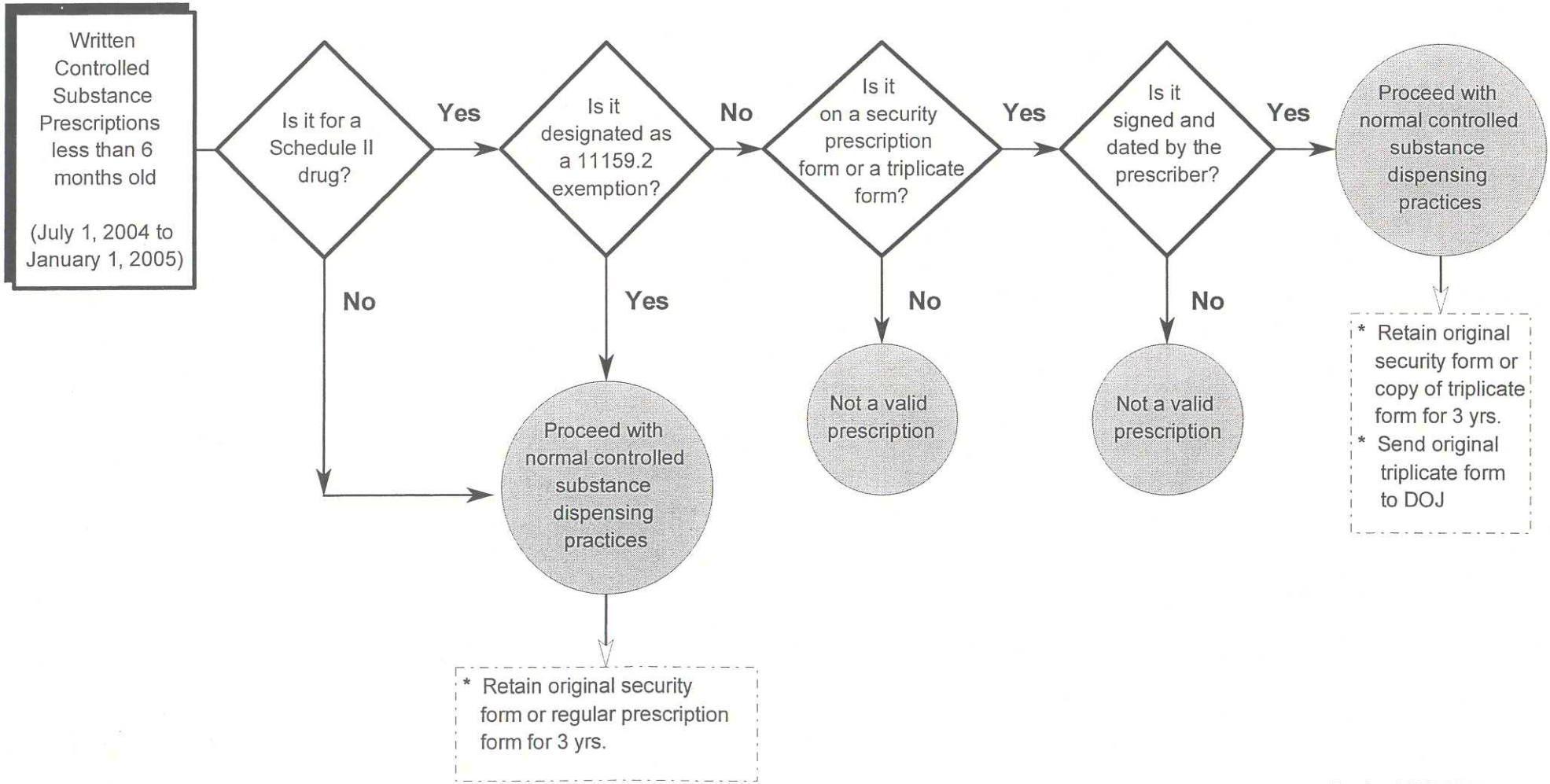
- Prescribers that dispense Schedule II controlled substances must report those prescriptions to the CURES system.

Written Controlled Substance Prescriptions



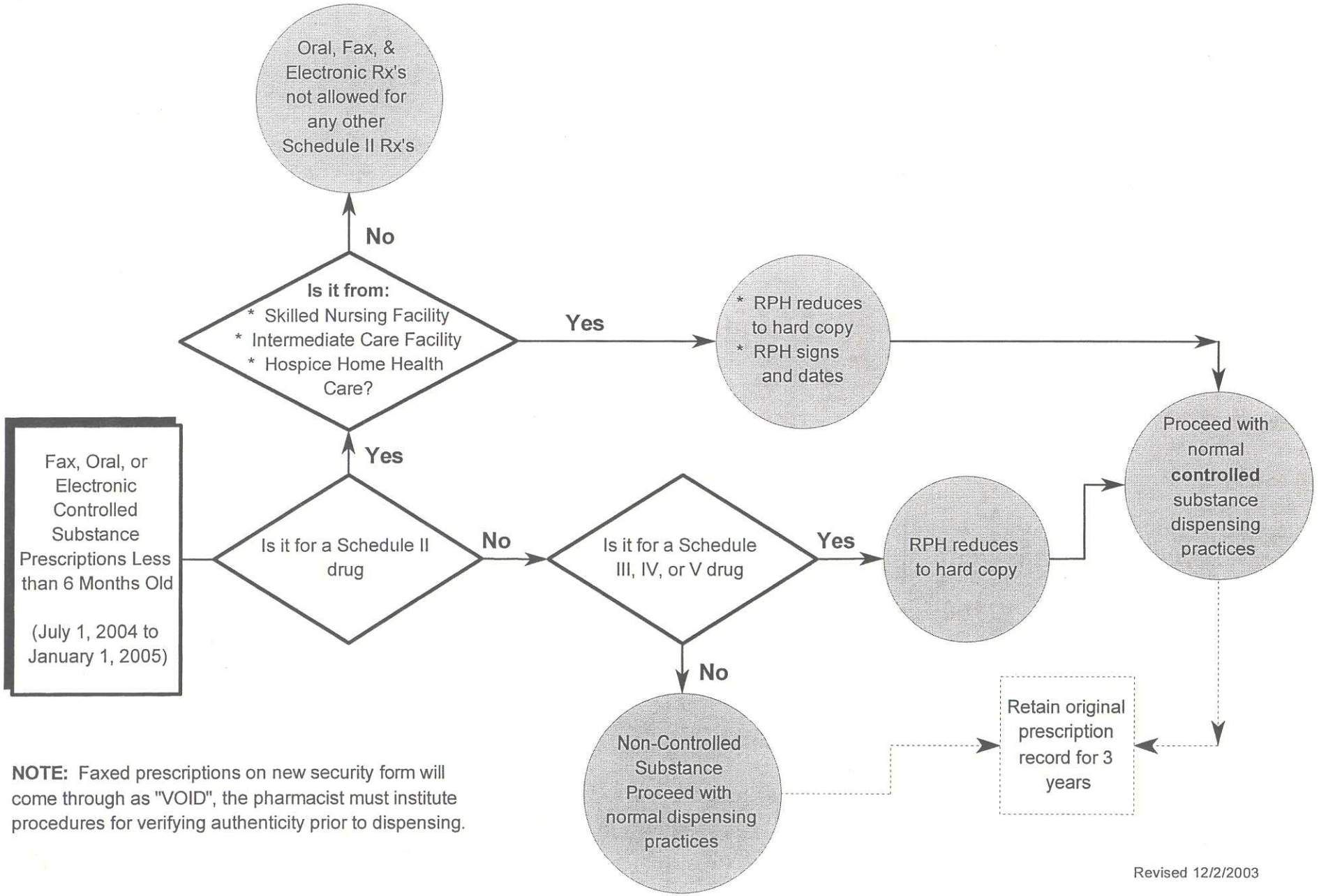
Revised 12/2/2003

Written Controlled Substance Prescriptions



Revised 12/2/2003

Oral, Fax, and Electronic Controlled Substance Prescriptions



NOTE: Faxed prescriptions on new security form will come through as "VOID", the pharmacist must institute procedures for verifying authenticity prior to dispensing.

Revised 12/2/2003

Agenda Item F

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: December 2, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Review of Quality Assurance Program**

In January 2002, the quality assurance regulation became effective and the board began its implementation. As you may recall, during the first six months of implementation (until July 1, 2002), the principal focus of the board's enforcement efforts were to educate pharmacists about the new regulation. If during this first six months, the pharmacy didn't have a quality assurance program, the inspector noted that on the inspection report and the pharmacy was requested to come into compliance. After July 1, 2002, failure to have a quality assurance program in place and/or failure to complete a quality assurance review would have resulted in notification to the licensee, with a possible referral for additional action by the board such as the issuance of a citation and fine.

In July 2003, the board approved a proposed modification of CCR section 1711 to clarify the pharmacist's responsibility when notifying the patient and prescriber of a prescription error. This modification was at the request of the professional associations. The modification allows for the pharmacist's professional judgment when situations do not require immediate notification of the prescriber when a prescription error has occurred, and when the patient has not taken the wrong medication. This proposed regulation change is awaiting formal notification of the rulemaking process.

At the meeting, staff will be providing overall statistics regarding the implementation of the program and there will be an open discussion for further enhancements or modifications to the program.

Agenda Item G

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: November 26, 2003**

From: **Anne Sodergren**
Board of Pharmacy

Subject: **Overview of the Pharmacists Recovery Program**

Background

In 1985, legislation became effective creating the Pharmacists Recovery Program (PRP). This legislation requires the board to seek way and means to identify and rehabilitate pharmacists whose competency may be impaired due to the abuse of alcohol or other drugs, or due to mental illness, so that pharmacists and interns so afflicted may be treated and returned to the practice of pharmacy in a manner which will not endanger the public health and safety. The law requires the board to contract with one or more employee assistance programs to administer the PRP and to contract with a pharmacist's professional association to perform outreach and promote voluntary access to the program.

As required by statute, the program fulfills two distinct functions. The PRP serves as a diversion program to which the board may refer licentiates, where appropriate, either in lieu of or in addition to disciplinary action. The PRP is also a confidential source of treatment for pharmacists who enter the program on a voluntary basis and without the knowledge of the board. Irrespective of the type of referral into the program, all participants are afforded the same treatment opportunities in the PRP.

Board policy is to expedite a pharmacist's the entry into the PRP rather than wait until the completion of an investigation. This is done by an inspector who will refer a pharmacist informally into the PRP. This early intervention assists the licensee in his or her recovery, but more importantly protects the public. Early intervention and referral results in the pharmacist or interns receiving treatment and being monitored while the case is being investigated.

When determining if a participant should be referred to the PRP in lieu of discipline the executive officer considers several factors including:

1. Danger to the public
    a. If drugs were diverted
    b. Quantity of drugs diverted
    c. Injury to consumer
2. Variety and severity of violations
3. Severity of addition or habituation
4. Types of drugs used
5. Frequency and use pattern
6. Prior entrance into the PRP and other mitigating circumstances.

Current Program Overview

For the first time since the PRP's inception, the contract was to a new vendor last July. Along with six other boards and bureaus under the Department of Consumer Affair's Umbrella, the board contracts with Maximus to oversee the Pharmacist Recovery Program. To ensure a seamless transition for the participants, board staff has been working diligently with the new contractor to ensure consistency of care for those in the program.

The general contract requirements for the diversion program are the same for each of the board's with special nuances specific to each board's program. This ensures that all participants in the diversion/recovery programs receive consistent treatment, e.g., inpatient and/or outpatient treatment, health support groups, attendance at AA/NA meetings etc. Several of the boards, utilize Diversion Evaluation Committees (DECs) to monitor participant treatment and compliance in the program as allowed by their specific legislative authority. These meetings can prove costly to the participants who are required to travel to the meetings and also relinquishes the confidentiality and anonymity treatment programs usually adhere to as the participant must appear before the DECs.

The Board of Pharmacy does not have the statutory authority to establish or use DECs. Rather, the board uses a Pharmacy Review Committee (PRC) to review and determine the proper treatment for all board-referred participants (those referred either in addition to or in lieu of formal discipline). The PRC is comprised of the assigned Clinical Case Manager from Maximus, a Supervising Inspector and a staff manager trained in drug recognition and the treatment of substance abuse.

The PRC meets monthly to discuss participants' treatment contracts, compliance and assessment notes as well as to review any participant requests. At minimum each participant's treatment contract and compliance is reviewed on a quarterly basis. However, a participant's treatment contracts may be reviewed more frequently at the participant's request of if the participant is non compliant. All self-referred participants (and board informal) are monitored solely by the Clinical Case Manager therefore ensuring the confidentiality of those participants as required by statute. In the event that a self referred or board informal participant is deemed to be a threat to themselves or to the public, Maximus is required by law to notify the board. This is to ensure that the board's public protection mandate is met.

Ultimately, the board is responsible for public protection first and foremost. While ensuring licensees afflicted with mental illness or chemical dependency are treated and rehabilitated so they can return to the practice of pharmacy safely, this cannot be done at the expense of the board's mandate to protect the public.

Treatment Contracts

All participants entering the PRP are evaluated by a licensed clinician. The initial evaluation identifies the nature and severity of the problem. Initial recommendations are made regarding the treatment and an initial treatment contract is established based on the recommendations.

Rehabilitation plans for a chemically dependent participant typically include total abstinence from alcohol or other mood altering chemicals, inpatient or outpatient treatment, documented attendance 3-5 self-help groups such as Alcoholics Anonymous (AA) and/or Narcotics Anonymous (NA) per week and at least 1-2 support groups. The support groups are conducted under the guidance of a licensed clinician and are comprised of health care professionals in recovery. These support groups serve as a forum for health care professional

to discuss their recovery and may be used to confront a participant who may be acting inappropriately or who is not embracing recovery. A random body fluid testing scheduled is established usually averaging between 24 – 36 urines screens a year (depending on the length of sobriety and severity of the addiction). Failure to maintain sobriety results in the immediate suspension from practice and usually requires at least a 30 - 90 day stay in residential treatment. Upon completion of this residential treatment, outpatient treatment is typically required in addition to support group attendance and attendance at AA and/or NA meetings.

The Pharmacy Review Committee (PRC) will evaluate all board mandated participants progress in the program and determine when it is appropriate for the participant to return to work. The contract will specify the type of pharmacy practice which is acceptable, and any restrictions placed on that participant's practice, e.g. the participant must work with another pharmacist at all times, cannot supervise intern, etc. Prior to returning to work the participant must designate a work site monitor - - typically a pharmacist, who is in a supervisory capacity or at least one management step above the participant. The work site monitor must be aware of the PRP contract and provide regular assessment of the participant's work performance to the PRC members. As a participant continues to gain strength in recovery, the PRC, with approval of the executive officer, will gradually remove the restrictions placed on the pharmacist's practice and reduce the treatment contract requirements by reviewing compliance with the treatment contract, relapse history, if any, and seeking input from the support group leader.

PRP participation is usually a three to five year commitment depending on the severity of the drug abuse or mental illness. The mandatory length of participation must be at minimum one year unless two separate assessments are completed, both of which must conclude that the licensee is not appropriate for diversion. A transition phase, which may begin after at least 24 consecutive months of recovery and a minimum of 24 negative random body fluid tests allows the participant the opportunity to be responsible for his or her own recovery while still in the PRP. A participant who meets all the criteria set by the PRC for completion and who has demonstrated that he or she is a rehabilitated will be successfully completed from the PRP after completing this transition phase and a negative hair test.

About the Participant Population

Since the program inception, 539 pharmacists and interns have received services from the program and 472 participants have been closed out of the program.[1] Approximately 50% of the licensees enrolled in the program are either self-referrals or board informal referrals. Of the participants closed from the program, 109 participants were closed out for either non-compliance or failure to derive benefit. In all circumstances where a participant has been mandated into the program and fails to successfully complete the program, the board will pursue additional disciplinary action. If a participant was a self-referral, the board will also complete an investigation and take appropriate action if the licensee was identified by the contractor as posing a threat to the health and safety of the public.

During the last fiscal year the average age of new participants was between 35 – 54 years old. Practice settings at the time of enrollment for these new participants included 42% in the retail pharmacy, 30% in the hospital pharmacy and the balance working in an assortment of other work settings. Alcohol was the highest reported drug used by these new participants in the previous 12 months prior to enrollment. The other most frequently reported drugs used included Tussionex® (or the generic equivalent), Soma®, Valium®, Heroine®, Hydrocodone, Hydromorphone, Morphine.

Program Statistics[2]

	00/01	01/02[3]	02/03
Enrolled in the Program			
Self	10	9	10
Board Informal	1	2	3
In Lieu Of Discipline	6	14	9
In addition to Discipline	3	0	4
Total Enrolled	20	25	26
Closures from the Program			
Successful Completion	9	10	9
Dismissed Failure to Derive Benefit	1	1	3
Dismissed Non-compliance	5	4	11
Other*	4	3	2
Total Closed	19	18	25
Number of Participants at the end of FY	56	63	63

* Other includes participant death, move to another state, or determined ineligible.

Statistics as reported by Maximus through August 31, 2003. Historical data was provided to Maximus by Managed Health Network, the previous contractor.

[1] Statistics as reported by Managed Health Network
[2] Statistics through May 2002.

(1) Nature and severity of the act(s) or offense(s).
(2) Total criminal record.
(3) The time that has elapsed since commission of the act(s) or offense(s).
(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.
(5) Evidence, if any, of rehabilitation submitted by the licensee.

1770. Substantial Relationship Criteria

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

1771. Posting of Notice of Suspension

Any holder of a pharmacy permit whose permit is suspended shall post a notice provided by the Board of the Board's suspension order in a location conspicuous to the public. Such notice shall remain posted during the entire period of actual suspension. Failure to post the notice of suspension as required herein shall be a ground for further disciplinary action.

1772. Disciplinary Condition of Suspension

Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of licensure suspension shall not enter any pharmacy prescription area or engage in any pharmacy related service.

1773. Disciplinary Conditions of Probation of Pharmacist

(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:
(1) Obey all laws and regulations substantially related to the practice of Pharmacy;
(2) Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;
(3) Submit to peer review if deemed necessary by the Board;
(4) Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;
(5) Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation;
(6) Not supervise any registered interns nor perform any of the duties of a preceptor;
(7) The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.
(b) If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions;

(1) Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;
(2) Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;
(3) Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;
(4) If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.
(c) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

1774. Disciplinary Conditions of Probation of Permit

(a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to the Board shall be subject to the following conditions:
(1) Obey all laws and regulations substantially related to the practice of pharmacy;
(2) The permit, through its officer, partners or owners, shall report to the Board or its designees quarterly, either in person or in writing as directed; if the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;
(3) Cooperate with the Board in its inspectional program;
(4) Post or circulate notice of conditions of probation so that they are available to all employees involved in pharmacy operations;
(5) Submit the operation of the pharmacy to peer review if deemed necessary by the Board;
(6) Provide evidence that owners or officers are knowledgeable in the laws pertaining to pharmacy if deemed necessary by the Board.
(b) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Article 9. Citations and Fines

(Renumbered from Article 9.5, 9-11-2002)

1775. Citations and Fines

(a) A committee of the board may issue citations containing orders of abatement and fines for any violation of the Pharmacy Law or regulations adopted pursuant thereto. For the purposes of this article, "committee of the board"means a committee of board members appointed by the board president to consider investigations of alleged violations.
(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the individual personally or by certified mail.